Drugs recently approved or pending approval

CARDIZEM LA

The US Food and Drug Administration (FDA) has given approval to Biovail Corporation (Ontario, Canada) to market Cardizem LA (diltazem HCl) for the treatment of chronic stable angina. The effectiveness of Cardizem LA was evaluated in a randomized, double-blind, parallel-group, dose-response trial of patients (N = 311) with chronic stable angina. Evening doses of Cardizem LA at 180, 360, and 420 mg were compared with placebo and to 360 mg Cardizem LA administered in the morning. All Cardizem LA doses administered at night increased exercise tolerance when compared with placebo after 21 hours. The mean effect (minus placebo) was 20 to 28 seconds for all doses, and no dose response was demonstrated. Cardizem LA 360 mg given in the morning also improved exercise tolerance after 25 hours. The most common adverse effects observed with Cardizem LA administration were lower-limb edema, dizziness, fatigue, bradycardia, first-degree atrioventricular block, and cough. Dosage for the treatment of angina should be individualized based on response. An initial dose of 180 mg once per day may be increased at intervals of 7 to 14 days if adequate response is not obtained. Cardizem LA previously has been approved for the treatment of hypertension.

KETEK

Aventis Pharmaceuticals, Inc. (Bridgewater, NJ) has been given approval by the FDA to market Ketek (telithromycin) for the treatment of acute bacterial exacerbation of chronic bronchitis (AECB) due to *Streptococcus pneumoniae, Haemophilis influenzae,* or *Moraxella catarrhalis*; acute bacterial sinusitis due to *Streptococcus pneumoniae, H. influenzae, M. catarrhalis,* or *Staphylococcus aureus*; and community-acquired pneumonia (CAP) due to *Streptococcus pneumoniae, H. influenzae, M. catarrhalis, Chlamydophila pneumoniae,* or *Mycoplasma pneumoniae* in patients older than 18 years. Ketek is the first in a new class of drugs known as ketolides. Ketek was evaluated in 4 randomized, double-blind, controlled trials and 4 open-label trials for CAP; 2 randomized, double-blind, comparative trials for acute sinusitis; and 3 randomized, double-blind, controlled trials for treatment of AECB. In CAP trials, Ketek-treated patients experienced more than an 88% clinical cure rate when compared with comparators (ie, clarithromycin, trovafloxacin, amoxicillin). In acute sinusitis studies, Ketek-treated patients (5-day treatment) experienced at least a 75% clinical cure rate when compared with comparator-treated patients (10-day treatment; amoxicillin/clavulanic acid, cefuroxime axetil). In AECB trials, Ketek-treated patients had at least an 85% clinical cure rate when compared with comparator-treated patients (ie, cefuroxime, amoxicillin/clavulanic acid, clarithromycin). The most commonly reported adverse effects associated with Ketek were nausea, headache, dizziness, vomiting, and diarrhea. The recommended dose of Ketek for AECB patients and acute bacterial sinusitis patients is 800 mg orally once daily for 5 days. CAP patients are recommended to take 800 mg orally once daily for 7 to 10 days.

VIOXX

Merck & Co., Inc., of Whitehouse Station, NJ, has been given FDA approval to market Vioxx (rofecoxib) for the acute treatment of migraine attacks with or without aura in adults. Vioxx was evaluated in 2 double-blind, placebo-controlled, outpatient trials (N = 1100). Patients were predominantly female and white, with a mean age of 40 years (range, 18–78 years). Patients were instructed to treat a moderate to severe headache. Doses of 25 mg and 50 mg were compared with placebo in the treatment of 1 migraine attack. A second dose of Vioxx was not allowed in either trial. Headache relief was defined as a reduction in headache severity from moderate or severe pain to mild to no pain and was assessed up to 2 hours after dosing. In both trials, the percentage of patients achieving headache relief 2 hours after treatment was significantly greater among Vioxx-treated patients at all doses as compared with placebo-treated patients (trial 1, 54% and 57% versus 34%; trial 2, 60% and 62% versus 30%). There were no statistically significant differences between the 25- and 50-mg dose groups. The most common adverse effects associated with Vioxx were dizziness, nausea, somnolence, and dyspepsia. The recommended starting dose of Vioxx is 25 mg once daily. The maximum recommended dose is 50 mg per day. Chronic daily use of Vioxx for the acute treatment of migraine is not recommended. Vioxx previously has been approved for the relief of signs and symptoms of osteoarthritis, relief of signs and symptoms of rheumatoid arthritis in adults, management of acute pain in adults, and treatment of primary dysmenorrhea.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Carbone, Hospital Physician, *125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*